

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF NEW YORK

----- X  
ONY, Inc., :  
 :  
Plaintiff, :  
 :  
-against- :  
 :  
Cornerstone Therapeutics, Inc., et al., :  
 :  
Defendants. :  
----- X

Case No. 11-cv-1027-WMS

**ORAL ARGUMENT REQUESTED**

**MEMORANDUM OF LAW IN SUPPORT OF  
DEFENDANTS PREMIER, INC.'S MOTION TO DISMISS FOR FAILURE  
TO STATE A CLAIM**

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**TABLE OF CONTENTS**

	<b>Page</b>
TABLE OF AUTHORITIES .....	ii
PRELIMINARY STATEMENT .....	1
STATEMENT OF FACTS .....	1
LEGAL STANDARD .....	3
ARGUMENT .....	3
I. ONLY FAILED TO PLEAD A FALSEHOOD. ....	4
II. ONLY FAILED TO PLEAD ACTUAL MALICE.....	7
III. ONLY FAILED TO PLEAD SPECIAL DAMAGES. ....	8
CONCLUSION .....	10

# **TABLE OF AUTHORITIES**

## **FEDERAL CASES**

	<b>Page</b>
<i>Ashcroft v. Iqbal</i> , 556 U.S. 662, 129 S. Ct. 1937 (2009) .....	3, 8
<i>ATSI Comms., Inc. v. Shaar Fund, Ltd.</i> , 493 F.3d 87 (2d Cir. 2007) .....	3
<i>Bell Atl. Corp. v. Twombly</i> , 550 U.S. 544 (2007) .....	3
<i>Celle v. Filipino Reporter Enters.</i> , 209 F.3d 163 (2d Cir. N.Y. 2000) .....	4
<i>Chamilia, LLC v. Pandora Jewelry, LLC</i> , No. 04-CV-6017, 2007 U.S. Dist. LEXIS 71246 (S.D.N.Y. Sept. 24, 2007).....	7
<i>Conyers v. Rossides</i> , 558 F.3d 137 (2d Cir. 2009) .....	3, 5
<i>Edward B. Beharry &amp; Co., Ltd. v. Bedessee Imps., Inc.</i> , No. 09-CV-0077, 2010 U.S. Dist. LEXIS 27404 (E.D.N.Y. March 23, 2010) .....	9
<i>Fashion Boutique of Short Hills, Inc. v. Fendi USA, Inc.</i> , 314 F.3d 48 (2d Cir. 2002) .....	9
<i>Fashion Boutique of Short Hills, Inc. v. Fendi USA, Inc.</i> , 75 F. Supp. 2d 235 (S.D.N.Y. 1999) .....	4, 8
<i>Gorran v. Atkins Nutritionals, Inc.</i> , 464 F. Supp. 2d 315 (S.D.N.Y. 2006), <i>aff'd</i> 279 Fed. App'x 40 (2d Cir. 2008).....	7
<i>Henry v. United Parcel Serv., Inc.</i> , 379 Fed. App'x 11 (2d Cir. 2010) .....	3
<i>Kirby v. Wildenstein</i> , 784 F. Supp. 1112 (S.D.N.Y. 1992) .....	8, 9, 10

## Page

<i>Levin v. McPhee</i> , 119 F.3d 189 (2d Cir. 1997) .....	4
<i>Mapinfo Corp. v. Spatial Reengineering Consultants</i> , No. 02-CV-1008, 2006 U.S. Dist. LEXIS 70408 (N.D.N.Y. Sept. 28, 2006) .....	4, 8
<i>McMillan v. Togus Reg'l Office, Dep't of Veteran Affairs</i> , 294 F. Supp. 2d 305 (E.D.N.Y. 2003), <i>aff'd</i> 120 Fed. App'x 849 (2d Cir. 2005).....	7
<i>Milkovich v. Lorain Journal Co.</i> , 497 U.S.1 (1990) .....	6, 7
<i>Moldea v. N.Y. Times Co.</i> , 22 F.3d 310 (D.C. Cir. 1994).....	7
<i>Murphy-Higgs v. Yum Yum Tree, Inc.</i> , 112 Fed. App'x 796 (2d Cir. 2004) .....	8, 9
<i>Verizon Directories Corp. v. Yellow Book USA, Inc.</i> , 309 F. Supp. 2d 401 (E.D.N.Y. 2004).....	4, 8

## STATE CASES

<i>Brian v. Richardson</i> , 87 N.Y.2d 46 (1995).....	4, 5
<i>Drug Research Corp. v. Curtis Publ'g Co.</i> , 7 N.Y.2d 435 (1960).....	4, 8-10
<i>Gross v. N.Y. Times Co.</i> , 82 N.Y.2d 146 (1993).....	6
<i>Immuno AG v. Moor-Jankowski</i> , 77 N.Y.2d 235 (1991).....	4-7
<i>Mann v. Able</i> , 10 N.Y.3d 271 (2008).....	4, 5
<i>Marlin Fire Arms Co. v. Shields</i> , 171 N.Y. 384 (1902).....	8

	<b>Page</b>
<i>Steinhilber v. Alphonse</i> , 68 N.Y.2d 283 (1986).....	5, 6

**FEDERAL RULES OF CIVIL PROCEDURE**

Fed R. Civ. Proc. 12(b)(6) .....	3
Fed. R. Civ. Proc. 8(a)(2) .....	3

### **PRELIMINARY STATEMENT**

In asserting an injurious falsehood claim against Defendant Premier, Inc.<sup>1</sup>, Plaintiff ONY, Inc. asks the court to intervene in a scientific debate. ONY complains that a scientific, peer-reviewed article co-authored by Premier employee Frank Ernst, which discusses the results of a study of medical data maintained in a Premier database, stated unreliable conclusions. According to ONY, the authors' conclusions are flawed because they failed to consider certain data that ONY believes should have been considered. While ONY characterizes the authors' conclusions as "false" – thereby implying that they are statements of *fact* – ONY's real complaint is that the authors' scientific *opinions* are wrong. Such a disagreement over opinion is not actionable under New York law. This type of debate belongs in scientific journals and medical conferences, not the courts. Plaintiff's claim for injurious falsehood must be dismissed because it fails to allege that defendants made false statements of fact. Additionally, ONY has failed to plead special damages and actual malice, both of which are essential elements of an injurious falsehood claim.

### **STATEMENT OF FACTS**

ONY's cause of action for injurious falsehood arises from an article co-authored by Premier's employee, Defendant Frank Ernst, with Defendants Rangasamy Ramanathan, Jatinder Bhatia and Krishnamurthy Sekar, entitled *Mortality in preterm infants with respiratory distress syndrome treated with poractant alfa, calfactant or beractant: a retrospective study* (the "Article"). (Compl. ¶¶ 35, 101; Declaration of M. Banas dated Dec. 8, 2011 ("Banas Decl.") Exh. B.) The Article concerns three surfactant drugs used to treat respiratory distress syndrome in premature infants: poractant alfa (Curosurf®), which is manufactured by Defendant Chiesi

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<sup>1</sup> All of Premier's arguments apply equally to Defendant Frank Ernst who joins in this Motion in the event that the Court decides it has jurisdiction over him.

Farmaceutici S.p.A. (“Chiesi”); calfactant (Infasurf®), which is manufactured by ONY; and beractant (Survanta®), which is manufactured by Abbott Pharmaceuticals. (*Id.* ¶¶ 20-22.) The Article was published on September 1, 2011, in “open access” format (*i.e.*, on the internet) in the Journal of Perinatology, which ONY describes as the preeminent publication for practitioners in the field of neonatology. (*Id.* ¶¶ 39, 55.)

ONY alleges that, in the Article, “the false claim is . . . made that preterm infants treated with Curosurf® have lower mortality than those treated with Infasurf®.” (*Id.* ¶¶ 35, 55.) According to ONY, this conclusion is “false” because it omitted “key data,” namely data on the patients’ length of stay in the hospital, “that is necessary for an accurate interpretation” of mortality data. (*Id.* ¶ 35; *see also* ¶ 37.) ONY claims that the authors deliberately omitted the length-of-stay data “to postulate, promote and disseminate false conclusions” favoring Chiesi’s product. (*Id.*) As a result of this alleged omission, ONY asserts that “the conclusions of the Article are unreliable, and therefore misleading. Had the Article presented the Curosurf® patients as having both a lower mortality and a shorter length of stay, it would be obvious that the differences in the results were a result of the differences in the groups of patients treated, **not** of any differences in the effect of the particular lung surfactant administered.” (*Id.* ¶ 67 (emphasis in original).)

As its Fifth Claim for Relief, ONY alleges that Premier, through its employee Frank Ernst, and the other authors are liable for injurious falsehood as a result of their submission of the Article for publication. (*Id.* ¶ 101.) ONY alleges that Premier and the authors “knew that the contents of the Article were false,” submitted the article “with reckless disregard of its reliability and falsity,” and that they “knew or should have known that the Article would harm Plaintiff.” (*Id.* ¶¶ 102-04.) As a result of the Article’s publication, ONY claims that it has suffered lost

sales, diminution in the value of its Infasurf® brand, a 10% or \$7.6 million loss in the inherent value of its business due to lost sales of Infasurf®, lessened borrowing capacity, and reduced ability to attract capital and talent. (*Id.* ¶ 106.) Finally, ONY alleges that, as a result of the injurious falsehood, it “has been damaged in an amount to be determined upon the trial of this action.” (*Id.* ¶ 107.)

### **LEGAL STANDARD**

A motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) assesses the legal feasibility of the complaint, and a complaint should be dismissed when it fails “to state a claim upon which relief can be granted.” Fed. R. Civ. P. 12(b)(6). Although the court must accept as true all factual allegations in the complaint, “courts are not bound to accept as true a legal conclusion couched as a factual allegation.” *Conyers v. Rossides*, 558 F.3d 137, 143 (2d Cir. 2009) (internal quotations omitted). “Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.” *Ashcroft v. Iqbal*, 556 U.S. 662, 129 S. Ct. 1937, 1950 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). “To survive dismissal, the plaintiff must provide the grounds upon which [plaintiff’s] claim rests through factual allegations sufficient ‘to raise a right to relief above the speculative level.’” *Henry v. United Parcel Serv., Inc.*, 379 Fed. App’x 11, 12 (2d Cir. 2010) (quoting *ATSI Comms., Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 98 (2d Cir. 2007) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007))). “Where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged – but it has not ‘show[n]’—‘that the pleader is entitled to relief.’” *Iqbal*, 129 S. Ct. at 1950 (quoting Fed. Rule Civ. Proc. 8(a)(2)).

### **ARGUMENT**

To establish a claim for injurious falsehood under New York law, a plaintiff must satisfy four essential elements: “(1) the falsity of the alleged statements; (2) publication to a third



person; (3) malice; and (4) special damages.” *Drug Research Corp. v. Curtis Publ’g Co.*, 7 N.Y.2d 435, 440 (1960); *see also Fashion Boutique of Short Hills, Inc. v. Fendi USA, Inc.*, 75 F. Supp. 2d 235, 239 (S.D.N.Y. 1999); *Mapinfo Corp. v. Spatial Reengineering Consultants*, No. 02-CV-1008, 2006 U.S. Dist. LEXIS 70408, \*40 (N.D.N.Y. Sept. 28, 2006); *Verizon Directories Corp. v. Yellow Book USA, Inc.*, 309 F. Supp. 2d 401, 406 (E.D.N.Y. 2004).

# **I. ONLY FAILED TO PLEAD A FALSEHOOD.**

Only assertions of fact, not opinion, can be proven false and subject to a claim of injurious falsehood. *Brian v. Richardson*, 87 N.Y.2d 46, 51 (1995). Moreover, statements of opinion are entitled to absolute protection under the New York Constitution. *Celle v. Filipino Reporter Enters.*, 209 F.3d 163, 178 (2d Cir. 2000); *Immuno AG v. Moor-Jankowski*, 77 N.Y.2d 235, 255 (1991) (expressions of “pure” opinion receive absolute constitutional protection under the New York Constitution). Where “a statement of opinion either discloses the facts on which it is based or does not imply the existence of undisclosed facts, the opinion is not actionable.” *Levin v. McPhee*, 119 F.3d 189, 197 (2d Cir. 1997).

Whether a statement is one of fact or opinion is a question of law. *Mann v. Able*, 10 N.Y.3d 271, 276 (2008). Factors considered by New York courts in distinguishing between opinion and fact include:

(1) whether the specific language in issue has a precise meaning which is readily understood; (2) whether the statements are capable of being proven true or false; and (3) whether either the full context of the communication in which the statement appears or the broader social context and surrounding circumstances are such as to signal . . . readers or listeners that what is being read or heard is likely to be opinion, not fact.

*Id.* (quoting *Brian*, 87 N.Y.2d at 51). In assessing the context of a statement, the court must look “at the content of the whole communication, its tone and apparent purpose” to determine whether a reasonable reader would have understood the statement to convey facts, rather than opinion.

*Immuno AG*, 77 N.Y.2d at 254 (quoting *Steinhilber v. Alphonse*, 68 N.Y.2d 283, 293 (1986)); *Mann*, 10 N.Y.3d at 276. “Rather than sifting through a communication for the purpose of isolating and identifying assertions of fact, the court should look at the overall context in which the assertions were made and determine on that basis ‘whether the reasonable reader would have believed the challenged statements were conveying facts about the libel plaintiff.’” *Brian*, 87 N.Y.2d at 51 (quoting *Immuno AG*, 77 N.Y.2d at 254).

The statement challenged by ONY – that preterm infants treated with Curosurf® have lower mortality than those treated with Infasurf® – reasonably can be understood only as a statement of the authors’ scientific opinion based on their interpretation of data disclosed in the Article. In asserting that this statement is “false,” ONY has made the implicit legal conclusion, which the Court need not accept, that the statement constitutes fact rather than opinion. *See Conyers v. Rossides*, 558 F.3d at 143. Yet, the allegations of ONY’s complaint demonstrate only that it has a difference of scientific opinion about the appropriate interpretation of mortality data. ONY does not allege that the authors of the Article falsely reported the mortality data underlying the Article’s findings. Rather, ONY complains that the ultimate conclusion the authors drew from that data – that infants treated with ONY’s product were more likely to die than infants treated with Chiesi’s product – is invalid because the authors did not consider the infants’ length of stay. Evidently, in ONY’s view, without considering length of stay, reliable conclusions cannot be drawn about the likelihood of mortality among patients treated with one drug compared to patients treated with another drug. This critique itself reveals that the nature of the statement at issue is scientific opinion or interpretation, which cannot be proven objectively true or false, but only more or less reliable depending on the methodology of study.

Furthermore, even if ONY is correct that reliable conclusions cannot be reached without considering length of stay, the intended audience of the Article – physicians and other scientists in the field of neonatology – are sophisticated enough to understand that length-of-stay data was not included in the study and to evaluate the validity of the authors’ findings. (*See* Compl. ¶ 39 (“The Journal is the primary and preeminent publication for practitioners in the field of neonatal-perinatal medicine, also called neonatology.”) Like the readers of the allegedly libelous statements at issue in *Immuno AG*, which the New York Court of Appeals found to be non-actionable opinions, the Journal of Perinatology “is directed to a highly specialized group of readers – medical doctors, researchers and the medical and science libraries of academic institutions. The average reader is thus likely not a novice in the field.” 77 N.Y.2d at 253. Moreover, the Article at issue here discloses the authors’ methodology and the facts on which their findings are based, as well as the limitations of their study. (*See* Banas Decl. Exh. B at 2, 5-6.) In this context, the average reader of the Article would understand that the authors’ conclusions are opinions based on the data disclosed. As courts have recognized, “a proffered hypothesis that is offered after a full recitation of the facts on which it is based is readily understood by the audience as conjecture.” *Gross v. N.Y. Times Co.*, 82 N.Y.2d 146, 154 (1993) (citing *Milkovich v. Lorain Journal Co.*, 497 U.S. 1, 28, n.5 (1990) (Brennan, J. dissenting)). Such statements signal to “readers or listeners that what is being read or heard is likely to be opinion, not fact.” *Id.* (quoting *Steinhilber*, 68 N.Y.2d at 292). Thus, the context of the Article clearly demonstrates that ONY is challenging a statement of opinion, not fact, and therefore has failed to plead the falsity element of its injurious falsehood claim.

Premier submits that the statement challenged by ONY reasonably cannot be construed as anything but opinion. However, in the event that the Court finds this issue to be a close call,

constitutional protections for freedom of speech require the Court to “err on the side of nonactionability.” *Moldea v. N.Y. Times Co.*, 22 F.3d 310, 317 (D.C. Cir. 1994). As the New York Court of Appeals has recognized in the context of a libel action, “[t]he chilling effect of protracted litigation can be especially severe for scholarly journals.” *Immuno AG*, 77 N.Y.2d at 249, 256. The constitutional concerns implicated here are particularly strong because the Article addresses a matter of public concern. *See Milkovich*, 497 U.S. at 20 (1990) (“[A] statement of opinion relating to matters of public concern which does not contain a provably false factual connotation will receive full constitutional protection.”); *Immuno AG*, 77 N.Y.2d at 256 (holding that the New York State Constitution protected a statement of opinion in a scholarly journal under “the cherished constitutional guarantee of free speech.”). Scientific matters generally are regarded as matters of public concern. *See Gorran v. Atkins Nutritionals, Inc.*, 464 F. Supp. 2d 315, 326 (S.D.N.Y. 2006), *aff’d* 279 Fed. App’x 40 (2d Cir. 2008); *McMillan v. Togus Reg’l Office, Dep’t of Veteran Affairs*, 294 F. Supp. 2d 305, 316 (E.D.N.Y. 2003), *aff’d* 120 Fed. App’x 849 (2d Cir. 2005). The speech at issue here concerns a topic of undeniable public importance – the efficacy of drugs for the treatment of disease in premature infants. Thus, the protection of free speech further supports dismissal of ONY’s injurious falsehood claim, to the extent that the Court finds that the challenged statement fairly could be construed either as fact or opinion.

## **II. ONY FAILED TO PLEAD ACTUAL MALICE.**

To state a claim for injurious falsehood under New York law, the plaintiff must allege facts demonstrating that the defendant acted with actual malice – *i.e.*, with knowledge that his statements were false or with reckless disregard for their truth or falsity. *Chamilia, LLC v. Pandora Jewelry, LLC*, No. 04-CV-6017, 2007 U.S. Dist. LEXIS 71246, \*35-\*36 (S.D.N.Y. Sept. 24, 2007). ONY’s complaint asserts only conclusory statements that Premier and the

authors “knew that the contents of the Article were false” and submitted the Article for publication “with reckless disregard of its reliability and falsity.” (Compl. ¶¶ 102-103.) Such “[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.” *Ashcroft v. Iqbal*, 556 U.S. 662, 129 S. Ct. 1937, 1950 (2009). Notably, ONY’s conclusion that Defendants acted with reckless disregard of the reliability of the Article is contradicted by facts alleged in the complaint that the Article was submitted for peer review and, it is implied, was recommended for publication by one of the two reviewers. (Compl. ¶¶ 49-50.) Therefore, ONY has failed to plead the malice element of its injurious falsehood claim.

### **III. ONY FAILED TO PLEAD SPECIAL DAMAGES.**

Special damages are an essential element of an injurious falsehood claim. *Murphy-Higgs v. Yum Yum Tree, Inc.*, 112 Fed. App’x 796, 797 (2d Cir. 2004); *Drug Research Corp. v. Curtis Publ’g Co.*, 7 N.Y.2d 435, 441 (1960) (“It is an established rule in New York that a libel on the product is actionable by the manufacturer only if special damages are alleged.” (citing *Marlin Fire Arms Co. v. Shields*, 171 N.Y. 384 (1902))). The requirements for pleading special damages are strictly interpreted. *Kirby v. Wildenstein*, 784 F. Supp. 1112, 1116 (S.D.N.Y. 1992). A complaint may be dismissed for failure to plead special damages because “proving special damages goes to the cause of action itself and not merely to the recovery.” *Id.* (internal citations omitted).

Under New York law, special damages are defined as economic or pecuniary loss, including loss of sales, arising from allegedly wrongful conduct. *Verizon Directories Corp.*, 309 F. Supp. 2d at 406; *Fashion Boutique, Inc.*, 75 F. Supp. 2d at 239. “Special damages must be fully and accurately stated, with sufficient particularity to identify actual losses.” *Alternative Electrodes, LLC v. EMPI, Inc.*, 597 F. Supp. 2d 322, 337 (E.D.N.Y. 2009) (quoting *Mapinfo*

*Corp.*, No. 02-CV-1008, 2006 U.S. Dist. LEXIS 70408 at \*40). The exact damages allegedly suffered must be itemized. Merely asserting a sum equaling the value of lost profits, without itemization, amounts only to general damages and is insufficient to establish special damages. *Drug Research Corp.*, 7 N.Y.2d at 440; *Murphy-Higgs*, 112 Fed. App'x at 797; *Fashion Boutique of Short Hills, Inc. v. Fendi USA, Inc.*, 314 F.3d 48, 59 (2d Cir. 2002). "If the special damage was a loss of customers . . . the persons who ceased to be customers, or who refused to purchase, must be named . . . . If they are not named, no cause of action is stated." *Drug Research Corp.*, 7 N.Y.2d at 440. In addition to the particularity requirement, a plaintiff must establish that special damages are "the natural and immediate consequence of the disparaging statements." *Kirby*, 784 F. Supp. at 1116 (internal citations omitted).

In *Drug Research Corporation v. Curtis Publishing Company*, 7 N.Y.2d 435, 437 (1960), the defendants wrote and published an article critical of the plaintiff's weight-loss pill. The New York Court of Appeals held that the plaintiff's claim for libel of the product must be dismissed due to the plaintiff's failure to allege special damages. *Id.* at 440. The Court found that the plaintiff had failed to identify any customers that were lost as the result of the defendant's alleged libelous statements. *Id.* Additionally, with regard to the plaintiff's alleged damages of \$5,000,000, the Court held that "[s]uch round figures, with no attempt at itemization, must be deemed to be a representation of general damages." *Id.* at 441. Likewise, in *Edward B. Beharry & Co., Ltd. v. Bedessee Imps., Inc.*, the plaintiff attempted to evade the special damages requirement by asserting "a loss in *sales*, not *customers*." No. 09-CV-0077, 2010 U.S. Dist. LEXIS 27404, \*29 (E.D.N.Y. March 23, 2010) (emphasis in original). In that case, the plaintiff alleged a 75% loss in sales due to customers purchasing fewer products, rather than an actual

loss of customers. *Id.* The court held the plaintiff had not pleaded special damages because round figures, without itemization or identification of customers, was insufficient. *Id.*

Similarly, ONY alleges only that it suffered “lost sales” and a diminution in value of its business as a proximate result of the Article’s publication. Specifically, ONY contends that the value of its business has decreased by 10%, including “\$7.6 million as measured by two times EBIDTA.” (Compl. ¶ 106). ONY further contends that this diminution in value has lessened ONY’s borrowing capacity and harmed its ability to attract capital and talent, and that it has suffered damages in an amount to be proven at trial. *Id.* It has not identified a single customer lost as a result of the publication of the Article. Such allegations of “round figures” and general damages – rather than specific, itemized damages – fail to satisfy the requirements for pleading special damages under New York law. *See Drug Research Corp.*, 7 N.Y.2d at 441.

Furthermore, ONY has failed to plead any facts demonstrating that its alleged damages were the “the natural and immediate consequence” of the publication of the Article. *Kirby*, 784 F. Supp. at 1116. The complaint states only the legal conclusion that ONY has been harmed “[a]s a proximate result of these Defendants’ actions.” (Compl. ¶ 106.) Nowhere in the complaint has ONY alleged that it has lost business or suffered some other economic harm as the direct consequence of someone having read the Article. Thus, ONY’s complaint has not adequately pleaded the special damages element of injurious falsehood.

### **CONCLUSION**

For all of the foregoing reasons, ONY’s Fifth Claim for Relief should be dismissed with prejudice.

Dated:

New York, New York.  
January 17, 2012

Respectfully submitted,

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